5   **Patent Application**
                    of
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                    for

10   **DIABETES MANAGEMENT SYSTEM AND METHOD FOR CONTROLLING
                    BLOOD GLUCOSE**

              CONTINUATION APPLICATION INFORMATION

15   This application is a continuation in part of application
     Ser. No. 08/781,278 filed January 10, 1997, which is hereby
     incorporated by reference. → *Now U.S. Patent No. 5,956,501,*

20   **FIELD OF THE INVENTION**

     The present invention relates generally to disease management
     systems, and in particular to a diabetes management system
     for predicting a future blood glucose value of a patient and
25   for recommending a corrective action to the patient when the
     future blood glucose value lies outside of a target range.

              DESCRIPTION OF PRIOR ART

30   Insulin dependent diabetes mellitus (IDDM) is caused by the
     auto-immune destruction of the insulin producing islets of
     Langerhans in the pancreas. Insulin replacement therapy is
     the interim treatment for IDDM until such time as islet
     transplants become feasible. Insulin lowers the
35   concentration of glucose in the blood, while food raises the

concentration of glucose in the blood. The challenge of
insulin therapy is to administer food and insulin in a manner
which maintains blood glucose concentrations in an acceptable
range, thereby avoiding hypoglycemia and hyperglycemia.

5

Hyperglycemia has adverse long term consequences for the
body. These consequences include kidney damage leading to
kidney failure, micro-enurisms in the retina causing
blindness, and the blocking of capillaries in the extremities
10   causing an inability to heal wounds and subsequent gangrene.
Hypoglycemia has an immediate adverse consequence of reduced
brain function which leads to confusion and an inability to
reason, remember, or react. In the extreme, hypoglycemia
causes seizure, coma, and death.

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The first insulin used by diabetes patients was regular
insulin taken from beef or pig pancreases. This insulin
lasts for about six hours, so that patients were required to
inject it three or four times per day. After World War II,
20   longer acting insulin was developed by binding regular
insulin to protamine and zinc. Regular insulin dissociates
slowly from protamine and zinc, extending insulin action to
twelve hours for intermediate acting insulin and twenty-four
hours for ultra-lente insulin. Patients enjoyed reducing
25   injections to one per day, but were required to modify their
eating to a snack-all-day regimen to avoid hypoglycemia. The
one daily insulin dose was adjusted as needed to reduce the
incidence of both hypoglycemia and hyperglycemia.

30   The development of portable blood glucose meters encouraged
the development of more sophisticated insulin therapy
regimens. One of these regimens is the split/mixed regimen
which consists of two daily doses of mixed regular and
intermediate acting insulins taken before breakfast and
35   dinner. These four insulin therapy components are adjusted

using blood glucose values measured before each meal and at bedtime.   Patients using the split/mixed regimen are required to eat substantially the same meals every day so that the four insulin components may be adapted to the consistent meal pattern over time.

The split/mixed regimen has the advantage of allowing independent adjustment of insulin doses for each meal and requires only two injections per day.   However, it has several disadvantages which are primarily due to the intermediate acting insulin components.   The intermediate acting insulin taken before breakfast affects lunch time and pre-dinner blood glucose, requiring a patient to commit to the size and timing of lunch before eating breakfast.   The broad action of the intermediate acting insulin may lead to hypoglycemia before or after lunch when the size or timing of the lunch is varied.   Similarly, the intermediate acting insulin taken before dinner requires the patient to eat a snack at bedtime to mitigate nocturnal hypoglycemia.   Even when a snack is eaten, the intermediate acting insulin may cause hypoglycemia around 3 AM when its action peaks.

Many of the disadvantages of the split/mixed regimen are overcome in a second insulin therapy regimen called the basal/bolus regimen.   The basal/bolus regimen attempts to emulate the method by which an intact pancreas controls blood glucose.   Normally, the intact pancreas produces a steady supply of basal insulin to accommodate the body's basic resting needs.   The pancreas handles meals by releasing a sharp impulse of bolus insulin in a first phase.   The sharp impulse of bolus insulin raises circulating insulin levels immediately.   The first phase is followed by a sustained level of heightened insulin release in a second phase.   The second phase continues until the body's blood glucose

concentration falls back to normal, at which point basal
levels are obtained once again.

In the basal/bolus regimen, the basal insulin releases are
emulated by two daily basal injections of intermediate acting
insulin, such as Lente or Neutral Protamine Hagedorn (NPH),
generally taken before breakfast and at bedtime. The bolus
insulin releases are emulated by bolus injections of regular
or fast acting lispro insulin taken before each meal. Fast
acting lispro insulin allows the bolus injections to emulate
the first phase action of the pancreas better than regular
insulin by reducing the delay before the insulin injection
takes effect and by shortening the overall duration of the
insulin's action.

Thus, the basal/bolus regimen generally includes four insulin
doses per day consisting of a pre-breakfast dose of
intermediate insulin combined with regular or lispro insulin,
pre-lunch and pre-dinner doses of regular or lispro insulin,
and a bedtime dose of intermediate insulin. The two basal
insulin doses accommodate the basic insulin needs of a
patient absent any perturbations due to food. Food is
handled by the bolus insulin doses, which the patient
attempts to tailor to the amount of food to be eaten.

Problems arise in the basal/bolus regimen when a patient
incorrectly estimates the dose of bolus insulin required for
a given meal. Too little insulin causes the patient to
develop hyperglycemia, while too much insulin causes the
patient to develop hypoglycemia. Hypoglycemia or
hyperglycemia may also result when the size of the meal is
varied without adequate adjustment of the bolus insulin dose.
Patients using the basal/bolus regimen are typically required
to eat substantially the same meals every day so that the

bolus insulin doses may be adapted to the consistent meal pattern over time.

Several electronic diabetes management systems have been developed to assist patients in the implementation of the split/mixed or basal/bolus regimens. One such system is disclosed in U.S. Patent 5,019,974 issued to Beckers on May 28, 1991. Beckers describes a master computer for developing a therapy program for a patient and for downloading the therapy program to a patient-operated recorder. The recorder reminds the patient of any therapy due and records that the therapy has been performed by the patient. Data from the recorder is subsequently fed back to the master computer to improve or alter the therapy program.

In using Backers' system, a patient must strictly adhere to the predetermined therapy guidelines in order for the therapy program to be effective. To make any therapy adjustments, the patient must upload data to the master computer, wait for the therapy adjustments, and strictly follow the adjusted guidelines. Thus, Beckers' system restricts the patient to a consistent meal plan, with no flexibility for adjusting the therapy program to meals of varying size or timing.

Following a consistent meal plan is extremely difficult, whether for diabetes treatment or weight loss. Rarely can a patient stick to a predetermined meal plan every day of his or her life. Consequently, Beckers' system is ineffective for assisting the patient in controlling blood glucose and avoiding hypoglycemia or hyperglycemia when the patient deviates from the plan during his or her normal course of behavior.

Moreover, Beckers' system lacks any mechanism for predicting the patient's future blood glucose concentration and is thus

unable to alert the patient to future hypoglycemia or
hyperglycemia resulting from an unusual meal or an
incorrectly estimated insulin dose taken for the meal.
Further, Beckers does not teach or describe any mechanism for
5   recommending to the patient a corrective action, such as a
supplemental insulin dose or carbohydrate supplement, when
the patient has a potential for future hypoglycemia or
hyperglycemia.

10   Another diabetes management system is disclosed in U.S.
Patent 4,731,726 issued to Allen on March 15, 1988. Allen
describes a system which includes a physician computer for
downloading therapy guidelines to a patient-operated
apparatus. The apparatus includes a blood glucose meter for
15   recording a patient's blood glucose values and keys for
entering patient data relating to diet, insulin, exercise,
stress, and symptoms of illness. The apparatus is programmed
to recommend insulin doses to the patient based upon the data
supplied.

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Unfortunately, Allen's system recommends insulin doses to the
patient based upon pre-meal blood glucose values only, as
stated in column 16, lines 42 - 44. This forces the patient
to wait until the next meal before he or she may take action
25   to correct hypoglycemia or hyperglycemia developed since the
previous meal. Further, Allen's system has no mechanism for
predicting the patient's future blood glucose concentration
based upon the patient's post-meal blood glucose value and
the insulin action remaining from insulin doses injected
30   before the meal. As a result, Allen's system is unable to
alert the patient to future hypoglycemia or hyperglycemia
resulting from the patient eating an unusual meal or taking
an incorrect insulin dose for the meal.

OBJECTS AND ADVANTAGES OF THE INVENTION

In view of the above, it is an object of the present
invention to provide a diabetes management system for
5   predicting a future blood glucose concentration of a patient
based upon the patient's current blood glucose concentration
and the insulin action remaining from previous insulin doses,
thereby enabling the patient to take timely corrective action
to prevent hypoglycemia or hyperglycemia. It is another
10   object of the invention to provide a diabetes management
system for recommending the corrective action to the patient
when the predicted blood glucose value lies outside of a
target range.

15   These and other objects and advantages will become more
apparent after consideration of the ensuing description and
the accompanying drawings.

SUMMARY

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The invention presents a system and method for assisting a
patient having diabetes mellitus in controlling blood
glucose. The system includes a patient-operated apparatus
having a blood glucose meter for measuring a blood sample of
25   the patient and for producing from a measurement of the blood
sample a blood glucose value $G(t_d)$ representative of a blood
glucose concentration of the patient at time t_d. The
apparatus also includes a user interface for entering in the
apparatus an insulin dose value I_k representative of an
30   insulin dose administered to the patient prior to time t_d.

The apparatus further includes a memory for storing maximum
and minimum values defining a target blood glucose range of
the patient. The memory also stores a target blood glucose
35   value of the patient within the range, an insulin sensitivity

value representative of an insulin sensitivity of the patient, and information for determining an insulin action value $F_k(t_d)$ representative of a fraction of insulin action remaining at time t_d from the insulin dose.

A processor is connected to the glucose meter, user interface, and memory. The processor is programmed to determine the insulin action value $F_k(t_d)$ and to determine a future blood glucose value $G(t_j)$ representative of an expected blood glucose concentration of the patient at time t_j. The processor determines the future blood glucose value $G(t_j)$ in dependence upon the blood glucose value $G(t_d)$, the insulin dose value I_k, the insulin sensitivity value, and the insulin action value $F_k(t_d)$. The processor is also programmed to determine a corrective action for the patient when the future blood glucose value $G(t_j)$ lies outside of the target range.

The corrective action is preferably an administration of a supplemental insulin dose when the future blood glucose value $G(t_j)$ lies above the target range or a consumption of a number of grams of carbohydrates when the future blood glucose value $G(t_j)$ lies below the target range. The processor is programmed to determine the supplemental insulin dose in dependence upon the insulin sensitivity value and a difference between the future blood glucose value $G(t_j)$ and the target blood glucose value. The processor is further programmed to determine the number of grams of carbohydrates to be consumed in dependence upon the difference between the future blood glucose value $G(t_j)$ and the target blood glucose value. A display is connected to the processor for displaying the future blood glucose value $G(t_j)$ and for recommending the corrective action to the patient.

The system also includes a healthcare provider computer in communication with the apparatus for receiving from the apparatus blood glucose values and insulin dose values and for calculating from the values an adjusted insulin

5   sensitivity value for the patient. The apparatus includes a communication device, such as a modem and input/output port, connected to the processor for establishing a communication link between the apparatus and the healthcare provider computer, for transmitting the blood glucose values and

10   insulin dose values through the communication link, and for receiving through the communication link the adjusted insulin sensitivity value.

BRIEF DESCRIPTION OF THE DRAWINGS

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FIG. 1   is a top plan view of a patient-operated apparatus according to the invention.

FIG. 2   is a schematic block diagram of the apparatus of FIG. 1 connected to a healthcare provider computer

20   through a communication network.

FIG. 3   is a schematic diagram of the apparatus of FIG. 1 connected to the healthcare provider computer of FIG. 2 through a connection cord.

FIG. 4   is a sample parameter value entry window as it

25   appears on a display of the apparatus of FIG. 1.

FIG. 5   is a graph illustrating the percent of insulin action remaining from regular and fast acting insulins as a function of time after injection.

FIG. 6A   is a sample table showing fractions of insulin

30   action remaining from a dose of regular insulin at corresponding time points after injection.

FIG. 6B   is a continuation of the table of FIG. 6A.

FIG. 7   is a sample table showing fractions of insulin action remaining from a dose of fast acting insulin

35   at corresponding time points after injection.

FIG. 8A   is a flow chart illustrating steps included in a
computer program executed by the apparatus of
FIG. 1.

FIG. 8B   is a continuation of the flow chart of FIG. 8A.

5   FIG. 9A   is a flow chart illustrating steps included in a
prediction program module of the computer program of
FIGS. 8A and 8B.

FIG. 9B   is a continuation of the flow chart of FIG. 9A.

FIG. 10   is a flow chart illustrating steps included in a

10   graph program module of the computer program of
FIGS. 8A and 8B.

DETAILED DESCRIPTION

15   The present invention is a diabetes management system and
method for predicting a future blood glucose value of a
patient and for recommending to the patient a corrective
action when the future blood glucose value lies outside of a
target blood glucose range. In the following description,

20   numerous specific details are set forth in order to provide a
thorough understanding of the present invention. However, it
will be apparent to one of ordinary skill in the art that
these specific details need not be used to practice the
invention. In other instances, well known structures,

25   interfaces, and processes are not shown in detail to avoid
unnecessarily obscuring the present invention.

FIGS. 1 - 7 illustrate a diabetes management system according
to a preferred embodiment of the invention. Referring to

30   FIG. 1, the diabetes management system includes a patient-
operated apparatus 10 having a housing 12 for holding the
components of apparatus 10. Housing 12 is preferably
sufficiently compact to enable apparatus 10 to be hand-held
and carried by a patient. A strip guide 18 for receiving a

35   blood glucose test strip 20 is located on a surface of

housing **12**.   Test strip **20** is for receiving a blood sample
from the patient.

Apparatus **10** includes a display **14** for displaying predicted
5   future blood glucose values and for recommending to the
patient corrective actions when the future blood glucose
values lie outside of a target blood glucose range. Display
14 is preferably a liquid crystal display (LCD). Display **14**
is also designed to display prompts and a menu **46** to the
10   patient during the operation of apparatus **10**.

Menu **46** preferably includes a number of menu options as
follows. The "DOSE" option starts a procedure for entering
in apparatus **10** insulin dose values representative of insulin
15   doses administered to the patient. Each insulin dose is
typically self-injected by the patient. After injecting a
dose, the patient selects the "DOSE" option to record in
apparatus **10** the dose value and the type of insulin injected.
The "TEST BG" option starts a procedure for measuring a
20   current blood glucose value of the patient. The "PREDICT"
option starts a procedure for predicting a future blood
glucose value of the patient.

The "VALUES" option starts a procedure for entering in
25   apparatus **10** various parameter values used to predict the
future blood glucose values and to recommend appropriate
corrective actions to the patient. The "SEND" option starts
a procedure for transmitting the blood glucose values and
insulin dose values stored in apparatus **10** to a healthcare
30   provider computer. The "RECEIVE" option starts a procedure
for receiving data from the healthcare provider computer.

Display **14** is also designed to display the predicted future
blood glucose values in graphical form. Display **14**
35   preferably displays a graph **48** which includes a blood glucose

value curve **50** generated from the predicted blood glucose values. Graph **48** also includes a hypoglycemic line **52** indicating a hypoglycemic threshold of the patient and a hyperglycemic line **53** indicating a hyperglycemic threshold of

5   the patient. Apparatus **10** also includes an audio transducer, such as a speaker **54**, for audibly alerting the patient when a predicted future blood glucose value lies below the hypoglycemic threshold.

10   Apparatus **10** further includes a keypad **16** having a number of keys as follows. The ON/OFF key is pressed to turn apparatus **10** on and off. Number keys 0, 1, 2, 3, etc. are used for entering information on display **14**, such as insulin dose values, insulin types, and dates and times of injections.

15   The ENTER key is used after operation of the number keys to enter the information in apparatus **10**. The ENTER key is also used to select menu options. The CLEAR key is used to clear numbers which have been entered incorrectly. The YES and NO keys are pressed in response to prompts on display **14** which

20   require a yes or no answer.

The MENU key is pressed to display menu **46** on display **14**. The ARROW keys are for scrolling through the menu options. Specific techniques for manufacturing and using an electronic

25   apparatus having these keys are well known in the art. Further, those skilled in the art will recognize that the keys may be replaced by other user controls, such as switches, buttons, or graphic controls implemented on a touch sensitive screen.

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FIG. 2 is a schematic block diagram illustrating apparatus **10** in greater detail. Apparatus **10** includes a microprocessor **22** and a memory **24** connected to microprocessor **22**. Microprocessor **22** is designed to execute a computer program

35   stored in memory **24** to perform the various calculations and

control functions which are described in the operation
section below.

Keypad **16** is connected to microprocessor **22** through a
standard keypad decoder **26**. Display **14** is connected to
microprocessor **22** through a display driver **30**.
Microprocessor **22** communicates with display driver **30** via an
interface, and display driver **30** updates and refreshes
display **14** under the control of microprocessor **22**. Speaker
54 and a clock **56** are also connected to microprocessor **22**.
Speaker **54** operates under the control of microprocessor **22** to
emit audible tones alerting the patient to possible future
hypoglycemia. Clock **56** supplies the current date and time to
microprocessor **22**.

Memory **24** also stores blood glucose values of the patient,
the insulin dose values, the insulin types, and the parameter
values used by microprocessor **22** to calculate future blood
glucose values, supplemental insulin doses, and carbohydrate
supplements. Each blood glucose value and insulin dose value
is stored in memory **24** with a corresponding date and time.
Memory **24** is preferably a non-volatile memory, such as an
electrically erasable read only memory (EEPROM).

Apparatus **10** also includes a blood glucose meter **28** connected
to microprocessor **22**. Glucose meter **28** is designed to
measure blood samples received on blood glucose test strips
and to produce blood glucose values from measurements of the
blood samples. Such glucose meters are well known in the
art. Glucose meter **28** is preferably of the type which
produces digital values which are output directly to
microprocessor **22**. Alternatively, blood glucose meter **28** may
be of the type which produces analog values. In this
alternative embodiment, blood glucose meter **28** is connected

to microprocessor **22** through an analog to digital converter (not shown).

Apparatus **10** further includes an input/output port **34**, preferably a serial port, which is connected to microprocessor **22**. Port **34** is connected to a modem **32** by an interface, preferably a standard RS232 interface. Modem **32** is for establishing a communication link between apparatus **10** and a healthcare provider computer **38** through a communication network **36**. Modem **32** is capable of transmitting data to and receiving data from provider computer **38** through communication network **36**. In the preferred embodiment, communication network **36** is a telephone network and modem **32** establishes the communication link to computer **38** through telephone lines.

Referring to FIG. 3, the input/output port may also be used to establish an alternative communication link between apparatus **10** and computer **38** through a data connection cord **40**. Connection cord **40** is connectable to the input/output port of apparatus **10** and to a corresponding input/output port of healthcare provider computer **38**. Specific techniques for connecting electronic devices through connection cords are well known in the art.

Healthcare provider computer **38** is preferably a personal computer located at a healthcare provider site, such as the office of the patient's physician. Healthcare provider computer **38** is designed to receive the patient's blood glucose values and insulin dose values from apparatus **10** and calculate from the values an adjusted insulin sensitivity value for the patient, as will be explained in the operation section below.

The computer program executed by microprocessor **22** includes
equations for calculating future blood glucose values,
supplemental insulin doses, and carbohydrate supplements.
The variables used in the computer program are defined as
5   follows:

$t_1, t_2, \ldots t_d, \ldots t_j, \ldots t_M$ = time points.

$G(t_d)$ =   blood glucose value representative of a blood
10   glucose concentration of the patient at time t_d.

$G(t_j)$ =   future blood glucose value representative of an
                  expected blood glucose concentration of the patient
                  at time t_j.

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I_k =   insulin dose value representative of an insulin
                  dose **k** administered to the patient prior to time
                  t_d, where k = 1 to N and N = the total number of
                  bolus and supplemental insulin doses administered
20   to the patient. Insulin dose value I_k is
                  preferably expressed in units of insulin.

P_k =   insulin type of insulin dose **k**, e.g. regular
                  insulin or fast acting lispro insulin.

25

$F_k(t_d)$ =   insulin action value representative of the fraction
                  of insulin action remaining at time t_d from insulin
                  dose **k**. For the purposes of this specification and
                  the appended claims, insulin action is defined as
30   the action of insulin to lower a patient's blood
                  glucose concentration.

$F_k(t_j)$ =   insulin action value representative of a fraction
                  of insulin action remaining at time t_j from insulin
35   dose **k**.

S =   insulin sensitivity value representative of an insulin
           sensitivity of the patient. Insulin sensitivity value **S**
           indicates the amount a unit of insulin is expected to
5   lower the patient's blood glucose concentration. Value **S**
           is a variable which is preferably updated in response to
           data collection from the patient, as described in detail
           below.

10 **D** =   a recommended supplemental dose of insulin calculated
           for the patient. Dose **D** is preferably expresses in
           units of insulin.

C =   carbohydrate value indicating the amount one gram of
15   carbohydrates is expected to raise the patient's blood
           glucose concentration.

R_{max}, R_{min} = maximum and minimum values, respectively,
                    defining a target blood glucose range of the
20   patient.

T =   target blood glucose value of the patient within the
           target blood glucose range.

25 **H** =   Hypoglycemic value indicating a hypoglycemic threshold
           of the patient below which a carbohydrate supplement is
           desired.

B =   the number of grams of carbohydrates to be consumed by
30   the patient in a recommended carbohydrate supplement.

With these definitions, future blood glucose value $G(t_j)$ is
calculated according to equation (1):

$$G(t_j) = G(t_d) - S\left[\sum_{k=1}^{N} I_k\left(F_k(t_d) - F_k(t_j)\right)\right] \quad (1)$$

Microprocessor **22** calculates future blood glucose value
G(t_j) from blood glucose value **G(t_d)**, insulin sensitivity

5   value **S**, insulin dose value **I_k**, and insulin action values
F_k(t_d) and **F_k(t_j)**. If the patient has injected multiple
insulin doses, their remaining action is summed as shown.
Blood glucose value **G(t_d)** is preferably measured a sufficient
time after the patient's last meal to ensure that most or all

10   of the meal has already been absorbed. A sufficient time is
usually two hours after a typical meal, or one hour after a
snack or smaller meal.

FIG. 4 shows a sample parameter value entry window **58** as it

15   appears on display **14**. Window **58** is preferably a pop-up
window displayed when the patient selects the "VALUES" option
from the menu. Window **58** includes data entry fields **60** for
entering in apparatus **10** insulin sensitivity value **S**,
carbohydrate value **C**, hypoglycemic value **H**, maximum value

20   **R_max**, minimum value **R_min**, and target value **T**. The patient
navigates between entry fields **60** using the arrow keys on the
keypad.

Apparatus **10** uses information derived from insulin time

25   activity profiles to determine the insulin action values.
The time activity profiles of insulin are described in
several sources, such as Eli Lilly and Company's website
http://www.lilly.com/diabetes/ref_manual/insulin_bck.html.
The time activity profiles of insulin are also described in

30   Howey et al. "A Rapidly Absorbed Analogue of Human Insulin",
Diabetes, Vol. 43, pp. 396-402, 1994, which is hereby
incorporated by reference.

FIG. 5 is a graph illustrating the percent of insulin action
remaining from doses of regular and lispro insulins as a
function of time after injection. The graph includes two
insulin action curves derived from data in Howey et al. A

5   first insulin action curve **42** shows the percent of insulin
action remaining from a dose of regular insulin as a function
of time after injection. A second insulin action curve **44**
shows the percent of insulin action remaining from a dose of
lispro insulin as a function of time after injection.

10

An insulin action value is determined from curves **42** or **44** by
determining the time after injection, locating the
corresponding percentage of insulin action remaining on the
appropriate curve, and dividing the percentage by 100 to

15   yield the insulin action value. For example, if the patient
injected a dose of lispro and the time after injection equals
150 minutes, then the insulin action value is determined to
be 0.40 from curve **44**. This indicates that at 150 minutes
after injection, the insulin dose has 40% of its full insulin

20   action remaining to lower the patient's blood glucose
concentration.

The insulin action curves shown in FIG. 5 are derived from
standard patient data. An insulin action curve customized to

25   an individual patient may be generated experimentally by
establishing basal homeostasis in the patient and then
measuring the effect of a supplemental insulin dose on the
patient's blood glucose concentration. After injecting the
supplemental insulin dose, the patient's blood glucose is

30   measured frequently over the period of time required for the
insulin to be fully absorbed.

The measured blood glucose values are used to generate a
curve of the patient's blood glucose concentration as a

35   function of time after injection. The total blood glucose

drop resulting from the supplemental insulin dose is
determined by subtracting the last blood glucose value from
the first blood glucose value. The curve is normalized by
subtracting the final blood glucose value from each point on
the curve and dividing the result by the total blood glucose
drop. Normalizing the curve in this manner yields an insulin
action curve individualized to the patient. This experiment
is repeated, preferably at varying times of day, to generate
a continuous insulin action curve for the patient.

In the preferred embodiment, information for determining
insulin action values $F_k(t_d)$ and $F_k(t_j)$ is stored in memory
24 in tabular form. The information may be derived from
standard insulin action curves or derived from an insulin
action curve individualized to the patient. FIGS. 6A and 6B
show a first insulin action Table 1 which is derived from
curve **42**, the insulin action curve for regular insulin.

FIG. 7 shows a second insulin action Table 2 which is derived
from curve **44**, the insulin action curve for lispro insulin.
Each insulin action table includes a first column containing
time points after injection and a second column containing
corresponding insulin action values. Microprocessor **22**
preferably uses linear interpolation to determine insulin
action values $F_k(t_d)$ and $F_k(t_j)$ from the insulin action
tables, as will be described in the operation section below.

The operation of the preferred embodiment is illustrated in
FIGS. 1 - 10. Referring to FIG. 2, a preferred method of
using the diabetes management system to assist a patient
having diabetes mellitus in controlling blood glucose
includes the step of storing in memory **24** insulin sensitivity
value **S**, carbohydrate value **C**, hypoglycemic value **H**, maximum
value R_{max}, minimum value R_{min}, target blood glucose value **T**,
and the table values for determining remaining insulin action

at corresponding times after injection. The values may be entered in apparatus **10** through input/output port **34** or keypad **16**. The values stored in memory **24** are preferably selected under the supervision of a healthcare provider, such

5   as the patient's physician.

Insulin sensitivity value **S** is preferably customized to the patient based upon the patient's measured blood glucose values and insulin dose values, as will be explained in

10   detail below. However, when the patient is first provided with apparatus **10**, historical blood glucose values and insulin dose values may not be available. In this case, insulin sensitivity value **S** is preferably estimated by dividing 1,500 mg/dl by the patient's total daily insulin

15   need. For example, if the patient's total daily insulin need is 30 units, the initial insulin sensitivity value is calculated as 50 mg/dl per unit of insulin.

Specific techniques for establishing carbohydrate value **C**,

20   hypoglycemic value **H**, maximum value R_{max}, minimum value R_{min}, and target blood glucose value **T** are well known in the art. For example, many physicians prefer a target blood glucose range of 100 - 150 mg/dl with a target blood glucose value of 120 mg/dl and a hypoglycemic value of 70 mg/dl. Carbohydrate

25   value **C** is preferably selected in dependence upon the patient's weight. For example, one gram of carbohydrates typically raises blood glucose concentrations by 3 mg/dl, 4 mg/dl, and 5 mg/dl for people who weigh 90 kg, 70 kg, and 45 kg, respectively.

30

Apparatus **10** is used by the patient to predict a future blood glucose value and to generate a corrective action when the predicted value lies outside of the patient's target blood glucose range. FIG. 8A is a flow chart illustrating steps

35   included in the computer program executed by microprocessor

22 to perform these functions. FIG. 8B is a continuation of
the flow chart of FIG. 8A.

In step **102**, microprocessor **22** determines if the patient has
5   selected the "DOSE" option from menu **46**. If the patient has
not selected the "DOSE" option, microprocessor **22** proceeds to
step **106**. If the patient has selected the "DOSE" option,
microprocessor **22** proceeds to step **104**, entering and storing
dose value I_k and insulin type P_k.
10

To enter and store dose value I_k and insulin type P_k,
microprocessor **22** displays the prompt "ENTER DOSE IN UNITS OF
INSULIN" on display **14**. The patient then enters dose value
I_k into microprocessor **22** through keypad **16**. The patient is
15   then prompted with "ENTER INSULIN TYPE: PRESS 1 FOR REGULAR
OR 2 FOR LISPRO". The patient enters insulin type P_k into
microprocessor **22** by pressing the key corresponding to the
insulin type injected.

20   Microprocessor **22** then prompts the patient with "ENTER
DATE/TIME OF INJECTION OR PRESS 1 FOR CURRENT DATE/TIME".
The patient enters the date and time of injection or selects
the current date and time if the dose entry is made
immediately after the injection. Microprocessor **22** stores
25   dose value I_k and insulin type P_k in memory **24** with the
selected date and time. Following step **104**, microprocessor
22 proceeds to step **106**.

In step **106**, microprocessor **22** determines if the patient has
30   selected the "TEST BG" option from menu **46**. If the patient
has not selected the "TEST BG" option, microprocessor **22**
proceeds to step **118**. If the patient has selected the "TEST
BG" option, microprocessor **22** prompts the patient to place a
blood sample on a blood glucose test strip and to insert the
35   test strip in strip guide **18**, step **108**.

Glucose meter **28** measures the blood sample and produces blood glucose value $G(t_d)$ from the measurement of the blood sample. In step **110**, blood glucose value $G(t_d)$ is entered in

5   microprocessor **22** by glucose meter **28**, coded and labeled with the date and time of the measurement, and stored in memory **24**. Blood glucose value $G(t_d)$ is also displayed to the patient on display **14** in step **112**.

10   In step **114**, microprocessor **22** determines if the patient has selected the "PREDICTION" option from menu **46**. If the patient has not selected the "PREDICTION" option, microprocessor **22** proceeds to step **118**. If the patient has selected the "PREDICTION" option, microprocessor **22** executes

15   a future blood glucose value program module in step **116**. The steps included in the future blood glucose value program module are illustrated in the flow chart of FIGS. 9A and 9B and will be described in detail below. After executing the program module of step **116**, microprocessor **22** proceeds to

20   step **118**.

In step **118**, microprocessor **22** determines if the patient has selected the "VALUES" option from menu **46**. If the patient has not selected the "VALUES" option, microprocessor **22**

25   proceeds to step **124**. If the patient has selected the "VALUES" option, microprocessor **22** displays on display **14** the parameter value entry window **58**, step **120**. In step **122**, the parameter values are entered in microprocessor **22** through keypad **16** and stored in memory **24**. Following step **122**,

30   microprocessor **22** proceeds to step **124**.

In step **124**, microprocessor **22** determines if the patient has selected the "SEND" option from menu **46**. If the patient has not selected the "SEND" option, microprocessor **22** proceeds to

35   step **128**. If the patient has selected the "SEND" option,

microprocessor **22** prompts the patient to connect modem **32** to
a telephone line. Microprocessor **22** then transmits the blood
glucose values and insulin dose values stored in memory **24** to
healthcare provider computer **38** through network **36**, step

5   **126**. Microprocessor **22** then proceeds to step **128**.

In step **128**, microprocessor **22** determines if the patient has
selected the "RECEIVE" option from menu **46**. If the patient
has not selected the "RECEIVE" option, microprocessor **22**

10   returns to step **102** and repeats the program steps until
apparatus **10** is turned off by the patient. If the patient
has selected the "RECEIVE" option, microprocessor **22** prompts
the patient to connect modem **32** to a telephone line. In step
130, microprocessor **22** receives data from healthcare provider

15   computer **38** through network **36**.

The data preferably includes an adjusted insulin sensitivity
value and may optionally include new maximum and minimum
values defining the patient's target blood glucose range, a

20   new target blood glucose value, and new insulin action table
values for determining remaining insulin action. In step
132, microprocessor **22** stores the received data in memory **24**
for use in subsequent calculations. Following step **132**,
microprocessor **22** returns to step **102** and repeats the program

25   steps until apparatus **10** is turned off by the patient.

FIGS. 9A and 9B illustrate the steps included in the future
blood glucose value program module of step **116**. In step
202, microprocessor **22** determines if the patient wishes to

30   see future blood glucose value $G(t_j)$ predicted for a default
ultimate time point by displaying the prompt "USE ULTIMATE
TIME IN PREDICTION? YES/NO?". In the preferred embodiment,
the ultimate time point is the time point at which the last
insulin dose **k** injected by the patient will be fully absorbed

35   and have no insulin action remaining. In response to a NO

input from the patient, microprocessor **22** proceeds to step **208**. In response to a YES input from the patient, microprocessor **22** sets time t_j equal to the ultimate time point, step **204**.

5

To set time t_j equal to the ultimate time point, microprocessor **22** retrieves from memory **24** the last insulin dose value I_k and corresponding insulin type P_k entered by the patient. If the insulin type P_k is regular insulin,

10 microprocessor **22** retrieves from Table 1 the time after injection value corresponding to 0.00 insulin action remaining, i.e. 720 minutes. If the insulin type P_k is lispro insulin, microprocessor **22** retrieves from Table 2 the time after injection value corresponding to 0.00 insulin

15 action remaining, i.e. 390 minutes.

Microprocessor **22** adds the retrieved time after injection value to the time of injection stored with the last dose value I_k and sets time t_j equal to the sum. When time t_j is

20 selected to be the ultimate time point, each insulin dose **k** injected by the patient will have no remaining insulin action at time t_j. Accordingly, microprocessor **22** sets insulin action value $F_k(t_j)$ equal to 0 for each dose value I_k stored in memory **24**, step **206**. Following step **206**, microprocessor

25 **22** proceeds to step **212**.

If the patient has not selected the ultimate time point for time t_j, microprocessor **22** prompts the patient to specify time t_j by displaying "ENTER TIME FOR PREDICTION". The

30 patient then enters time t_j in microprocessor **22** in step **208**. In step **210**, microprocessor **22** determines insulin action values $F_k(t_j)$ for each dose value I_k stored in memory **24**. Microprocessor **22** preferably determines insulin action values $F_k(t_j)$ using linear interpolation.

35

The insulin action value $F_k(t_j)$ for each dose value I_k is also determined in dependence upon its corresponding insulin type P_k. If the insulin type is regular insulin, microprocessor **22** determines the insulin action value $F_k(t_j)$

5   by interpolating between the values listed in Table 1. If the insulin type is lispro insulin, microprocessor **22** determines the insulin action value $F_k(t_j)$ by interpolating between the values listed in Table 2.

10   The interpolation is preferably performed as follows. For each dose value I_k, microprocessor **22** calculates a time after injection value X_k indicating the time differential between time t_j and the time of injection of dose **k**. Microprocessor **22** then retrieves four values from the appropriate insulin

15   action table. The four values retrieved are a first time after injection value X_0 and its corresponding insulin action value Y_0, and a second time after injection value X_1 and its corresponding insulin action value Y_1.

20   Value X_0 is selected from the appropriate table as the time after injection value which is closest to value X_k without exceeding value X_k. Value X_1 is selected as the time after injection value in the next row of the table. Microprocessor **22** preferably calculates the insulin action value $F_k(t_j)$ for

25   each dose value according to equation (2A):

$$F_k(t_j) = Y_0 + \frac{(X_k - X_0)(Y_1 - Y_0)}{(X_1 - X_0)} \qquad (2A).$$

For example, if the patient enters a dose value indicating a

30   dose of regular insulin was injected at 12:00 PM and specifies a time t_j of 2:20 PM, microprocessor **22** first calculates time after injection value X_k to be 140 minutes. Microprocessor **22** then retrieves from Table 1 the values X_0 = 135 minutes, Y_0 = 0.70, X_1 = 150 minutes, and Y_1 = 0.64.

Microprocessor **22** calculates insulin action value $F_k(t_j)$ for the dose from equation (2A) as:

$$F_k(t_j) = 0.70 + \frac{(140 - 135)(0.64 - 0.70)}{(150 - 135)} = 0.68$$

Microprocessor **22** thus determines that the regular insulin dose injected at 12:00 PM will have 68% of its insulin action remaining at 2:20 PM. Specific techniques for performing linear interpolations in this manner are well known in the art. Further, those skilled in the art will recognize that the insulin action tables could be provided with shorter time intervals between the time points to provide as much precision and accuracy as desired in the interpolation.

In step **212**, microprocessor **22** performs a similar linear interpolation to determine the insulin action values $F_k(t_d)$ for each dose value I_k stored in memory **24**. The insulin action value $F_k(t_d)$ for each dose value I_k is also determined in dependence upon its corresponding insulin type P_k. If the insulin type is regular insulin, microprocessor **22** determines the value $F_k(t_d)$ by interpolating between the values listed in Table 1. If the insulin type is lispro insulin, microprocessor **22** determines the value $F_k(t_d)$ by interpolating between the values listed in Table 2.

For each dose value I_k, microprocessor **22** calculates a time after injection value Z_k indicating the time differential between time t_d and the time of injection of dose **k**. Microprocessor **22** then retrieves from the appropriate insulin action table the first time after injection value X_0, the corresponding insulin action value Y_0, the second time after injection value X_1, and the corresponding insulin action value Y_1. Value X_0 is selected from the appropriate table as the time after injection value which is closest to value Z_k

without exceeding value Z_k. Value X_1 is selected as the time after injection value in the next row of the table. Microprocessor **22** calculates each insulin action value $F_k(t_d)$ according to equation (2B):

$$F_k(t_d) = Y_0 + \frac{(Z_k - X_0)(Y_1 - Y_0)}{(X_1 - X_0)} \qquad (2B).$$

For example, if the patient enters a dose value indicating a dose of lispro insulin was injected at 8:30 PM and time t_d is

10   11:00 PM, microprocessor **22** first calculates time after injection value Z_k to be 150 minutes. Microprocessor **22** then retrieves from Table 2 the values X_0 = 150 minutes, Y_0 = 0.40, X_1 = 165 minutes, and Y_1 = 0.32. Microprocessor **22** calculates insulin action value $F_k(t_d)$ for the dose from

15   equation (2B) as:

$$F_k(t_d) = 0.40 + \frac{(150 - 150)(0.32 - 0.40)}{(165 - 150)} = 0.40$$

Microprocessor **22** thus determines that the lispro insulin

20   dose injected at 8:30 PM has 40% of its insulin action remaining at 11:00 PM. In step **214**, microprocessor **22** calculates predicted future blood glucose value $G(t_j)$ according to equation (1):

$$G(t_j) = G(t_d) - S\left[\sum_{k=1}^{N} I_k\big(F_k(t_d) - F_k(t_j) \big) \right] \qquad (1)$$

Future blood glucose value $G(t_j)$ is then displayed to the patient on display **14**, step **216**. In step **218**, microprocessor **22** determines if the patient wishes to see

30   graph **48** by displaying the prompt "DISPLAY GRAPH? YES/NO?". In response to a NO input from the patient, microprocessor **22**

proceeds to step **222**. In response to a YES input from the patient, microprocessor **22** executes a graph program module in step **220**. The steps included in the graph program module are illustrated in the flow chart of FIG. 10 and will be

5   described in detail below. After executing the program module of step **220**, microprocessor **22** proceeds to step **222**.

In step **222**, microprocessor **22** compares future blood glucose value $G(t_j)$ to maximum value R_{max} and minimum value R_{min} to

10   determine if future blood glucose value $G(t_j)$ lies outside of the patient's target blood glucose range. If glucose value $G(t_j)$ does not lie outside of the target range, "NO CORRECTIVE ACTION REQUIRED" is displayed to the patient in step **224**. Following step **224**, the future blood glucose

15   value program module ends.

If glucose value $G(t_j)$ lies outside of the target range, microprocessor **22** determines a corrective action for the patient and recommends the corrective action to the patient

20   on display **14**. In step **226**, microprocessor **22** determines if glucose value $G(t_j)$ is greater than maximum value R_{max}. If glucose value $G(t_j)$ is not greater than maximum value R_{max}, microprocessor **22** proceeds to step **234**.

25   If glucose value $G(t_j)$ is greater than maximum value R_{max}, microprocessor **22** calculates a supplemental insulin dose **D** for the patient and displays insulin dose **D** on display **14**, step **228**. Microprocessor **22** preferably calculates supplemental insulin dose **D** in dependence upon insulin

30   sensitivity value **S** and a difference between future blood glucose value $G(t_j)$ and target blood glucose value **T** according to equation (3):

$$D = (G(t_j) - T)/S \qquad (3).$$

35

After displaying supplemental insulin dose **D**, microprocessor
22 determines if the patient wishes to enter a dose value for
the supplemental insulin dose by displaying the prompt
"SUPPLEMENTAL INSULIN TAKEN? YES/NO?", step **230**. In response

5   to a NO input from the patient, the program module ends. In
response to a YES input, microprocessor **22** proceeds to step
232, entering and storing the dose value and insulin type of
supplemental insulin dose **D**. Step **232** is analogous to step
104 previously described with reference to FIG. 7A.

10 Following step **232**, the program module ends.

In step **234**, microprocessor **22** determines if glucose value
G(t$_j$) is less than hypoglycemic value **H**. If future blood
glucose value **G(t$_j$)** is not less than hypoglycemic value **H**,

15 microprocessor **22** proceeds to step **240**. If glucose value
G(t$_j$) lies below hypoglycemic value **H**, microprocessor **22**
audibly alerts the patient by causing speaker **54** to emit
audible tones, step **236**. This alerts the patient that he or
she is likely to develop hypoglycemia unless a carbohydrate

20 supplement is taken.

In step **238**, microprocessor **22** calculates a number **B** of
grams of carbohydrates to be consumed by the patient and
displays a recommendation to consume number of grams **B**, step

25 **238**. Following step **238**, the program module ends.
Microprocessor **22** preferably calculates number of grams **B** in
dependence upon carbohydrate value **C** and the difference
between future blood glucose value **G(t$_j$)** and target blood
glucose value **T** according to equation (4):

30

$$B \;=\; (T \,-\, G(t_j))/C \qquad\qquad (4).$$

If future blood glucose value **G(t$_j$)** is not less than
hypoglycemic value **H**, then glucose value **G(t$_j$)** lies in a

35 range between hypoglycemic value **H** and minimum value **R$_{min}$**.

In this case, microprocessor **22** displays to the patient "POSSIBLE FUTURE HYPOGLYCEMIA: RECOMMEND SUBSEQUENT GLUCOSE MEASUREMENT IN 1.5 HOURS", step **240**. Following step **240**, the program module ends. Because the patient's blood glucose

5   concentration may rebound, it is presently preferred not to recommend a carbohydrate supplement unless future blood glucose value $G(t_j)$ is below hypoglycemic value **H**.

FIG. 10 is a flow chart illustrating the steps included in

10   the graph program module of step **220**. In steps **302** - **310**, microprocessor **22** generates a plurality of predicted future blood glucose values for various time points between time t_d and time t_j. The future blood glucose values are used to generate blood glucose value curve **50** of graph **48**. In the

15   preferred embodiment, the future blood glucose values are calculated for time points which increase from time t_d to time t_j.in five minute increments. It is obvious that the time increments may be varied as desired in alternative embodiments.

20

In step **302**, microprocessor **22** sets time t_j equal to time t_d plus five minutes. In step **304**, microprocessor **22** determines insulin action values $F_k(t_j)$ for each dose value I_k stored in memory **24**. Step **304** is analogous to step **210** previously

25   described with reference to FIG. 9A. In step **306**, microprocessor **22** calculates future blood glucose value $G(t_j)$. Step **306** is analogous to step **214** previously described with reference to FIG. 9A.

30   In step **308**, microprocessor **22** determines if time t_j is greater than or equal to the ultimate time point at which the last insulin dose **k** injected by the patient will have no insulin action remaining. If time t_j is not greater than or equal to the ultimate time point, microprocessor **22** sets time

35   t_j equal to time t_j plus five minutes, step **310**.

Microprocessor **22** then repeats steps **304** - **308** to calculate a subsequent future blood glucose value.

If time **t$_j$** is greater than or equal to the ultimate time point, microprocessor **22** generates blood glucose value curve **50** from the calculated future blood glucose values and displays graph **48** on display **14**, step **312**. Following step **312**, the graph program module ends. As shown in FIG. 1, graph **48** includes line **52** indicating the patient's hypoglycemic threshold and line **53** indicating the patient's hyperglycemic threshold. Lines **52** and **53** enable the patient to determine the time point at which he or she is predicted to develop hypoglycemia and hyperglycemia, respectively.

The diabetes management system of the present invention provides a significant improvement over conventional diabetes management systems by alerting the patient to the possible development of hypoglycemia or hyperglycemia between meals, thereby allowing the patient to take early corrective action. Conventional management systems are unable to account for the insulin action remaining from previous insulin doses and therefore restrict insulin supplements to pre-meal times. Thus, in using these conventional systems, the patient must wait until the next meal time to correct hyperglycemia, and may develop hypoglycemia without warning.

The following is an illustrative example of how apparatus **10** assists a patient in preventing hyperglycemia between meals. The example assumes the patient has an insulin sensitivity value of 40 mg/dl per unit, a target blood glucose range of 100 mg/dl - 150 mg/dl, a target blood glucose value of 120 mg/dl, a hypoglycemic value of 70 mg/dl, and a carbohydrate value of 4 mg/dl per gram.

In the example, the patient eats a late dinner at 8:40 PM. Before eating, the patient estimates that the meal requires 15 units of bolus insulin and injects 15 units of lispro at 8:30 PM. The patient records the dose value, dose type, and time of injection in apparatus **10**. At bedtime, 11:00 PM, the patient uses apparatus **10** to measure his or her blood glucose value. Apparatus **10** produces and displays to the patient a current blood glucose value of 480 mg/dl. The patient then requests apparatus **10** to predict a future blood glucose value at the ultimate time point.

Microprocessor **22** retrieves from memory **24** the dose value and corresponding insulin type of the dose injected by the patient at 8:30 PM. Microprocessor **22** calculates time after injection value Z_k to be 150 minutes. Microprocessor **22** then retrieves from Table 2 the values $X_0 = 150$ minutes, $Y_0 = 0.40$, $X_1 = 165$ minutes, and $Y_1 = 0.32$. Microprocessor **22** calculates insulin action value $F_k(t_d)$ from equation (2B) as:

$$F_k(t_d) = 0.40 + \frac{(150 - 150)(0.32 - 0.40)}{(165 - 150)} = 0.40.$$

Microprocessor **22** thus determines that the lispro insulin dose injected at 8:30 PM has 40% of its insulin action remaining at 11:00 PM. Microprocessor **22** also sets insulin action value $F_k(t_j)$ equal to 0.0 for each dose value stored in memory **24**. For simplicity of understanding, the example assumes that only the dose injected at 8:30 PM has remaining insulin action. Microprocessor **22** then calculates the predicted blood glucose value at 3:00 AM according to equation (1) as:

$$G(t_j) = 480 - 40(15 \times .40) = 240 \text{ mg/dl.}$$

This indicates that the patient can expect an ultimate blood glucose value of 240 mg/dl when the insulin dose has been completely absorbed. The predicted value of 240 mg/dl is greater than the patient's maximum value of 150 mg/dl, so

5 microprocessor **22** calculates a supplemental insulin dose for the patient and displays the recommended supplement on display **14**.   The supplemental dose **D** is calculated from equation (3) as:

10   **D** = (240 - 120)/40 = 3 units of supplemental insulin.

The patient takes the supplemental insulin dose and records the dose value in apparatus **10**. From taking the supplemental insulin dose, the patient obtains eight hours of normal blood

15 glucose in place of hyperglycemia. An adjusted insulin sensitivity may also be determined from the dose values and measured blood glucose values recorded in apparatus **10** as follows. The next morning, the patient measures his or her pre-breakfast blood glucose value using apparatus **10**. The

20 patient then transmits the recorded dose values and blood glucose values measured at bedtime and before breakfast to healthcare provider computer **38**.

An adjusted insulin sensitivity value is calculated in

25 healthcare provider computer **38** by subtracting the pre-breakfast blood glucose value from the bedtime blood glucose value. The result is divided by the total number of units of insulin which had remaining insulin action at bedtime. The number of units of insulin having remaining insulin action at

30 bedtime is equal to the total number of units of the supplemental insulin dose plus the fraction of any previously injected insulin doses having remaining action.

An illustrative example will now be given using the same

35 values presented above, where the patient's bedtime blood

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glucose value equals 480 mg/dl, the supplemental insulin dose value equals 3 units, and the fraction of insulin action remaining from a previous 15 unit insulin dose is 0.40. The present example further assumes a pre-breakfast blood glucose value of 138 mg/dl measured the following morning. The adjusted sensitivity value is calculated as:

$$S = (480 - 138)/(3 + (15 \times 0.40)) = 38 \text{ mg/dl per unit.}$$

The insulin sensitivity value S is preferably updated over time as a moving average of the individually calculated sensitivity values.

A second example illustrates how apparatus **10** assists a patient in preventing hypoglycemia. The second example assumes the same values presented in the first example except that the patient's blood glucose value at 11:00 PM is now assumed to be 280 mg/dl. Microprocessor **22** calculates the predicted glucose value at 3:00 AM from equation (1) as:

$$G(t_j) = 280 - 40(15 \times .40) = 40 \text{ mg/dl.}$$

The predicted value of 40 mg/dl is less than the patient's hypoglycemic value of 70 mg/dl. Accordingly, microprocessor **22** calculates a carbohydrate supplement and displays the number of grams of carbohydrates to be consumed by the patient. The number of grams of carbohydrates is calculated from equation (4) as:

$$B = (120 \text{ mg/dl} - 40 \text{ mg/dl})/4 = 20 \text{ grams.}$$

The patient consumes the carbohydrate supplement and successfully avoids hypoglycemia.

SUMMARY, RAMIFICATIONS, AND SCOPE

Although the above description contains many specificities, these should not be construed as limitations on the scope of the invention but merely as illustrations of the presently

5   preferred embodiment. Many other embodiments of the invention are possible. For example, the system of the invention may be implemented in many different hardware configurations. It is presently preferred to provide the patient with a small, portable apparatus to facilitate use of

10   the apparatus throughout the day. However, in alternative embodiments, the apparatus may comprise a personal computer, a multi-media processor connected to a television, or any other electronic device capable of performing the functions described.

15

Additionally, the system is not limited to establishing a communication link between the apparatus and healthcare provider computer through a telephone line or data connection cord. Those skilled in the art will recognize that the

20   apparatus may be placed in communication with the healthcare provider computer through a computer network, a wireless communication network, or a data storage card, such as a smart card, exchanged between the physician and patient. Specific techniques for establishing communication links

25   between a physician and a remotely located patient are well known in the art.

The insulin sensitivity values and insulin action values for determining remaining insulin action may differ in

30   alternative embodiments. The values shown in the preferred embodiment are exemplary of one possible embodiment of the invention and are not intended to limit its scope. Further, the insulin action values may be derived from standard data or derived from the blood glucose values and insulin dose

35   values of an individual patient. The insulin action values

may be further customized to the individual patient in dependence upon the patient's preferred mode of insulin administration, e.g. syringe injections into the thigh, gut, or arm, insulin pump administrations, or inhalation.

Further, the insulin action values need not be stored in tabular form. In an alternative embodiment, the apparatus stores first and second mathematical equations derived from the insulin action curves. The first equation expresses remaining insulin action as a function of time after injection of a dose of regular insulin. The second equation expresses remaining insulin action as a function of time after injection of a dose of lispro insulin. In this embodiment, the apparatus determines an insulin action value by determining the time after injection and calculating the insulin action value using the equation corresponding to the type of insulin injected.

The preferred embodiment includes a patient-operated apparatus and a healthcare provider computer in communication with the apparatus. This configuration of system components is presently preferred for ease of setting, storing, and adjusting the target blood glucose value and insulin sensitivity value of the patient under the supervision of a healthcare provider. However, those skilled in the art will recognize that the apparatus itself may also be programmed to adjust the patient's insulin sensitivity value based upon the stored blood glucose values and insulin dose values, eliminating the need for the healthcare provider computer if physician review is deemed unnecessary.

It is presently preferred to include a blood glucose meter in the apparatus for automated entry of blood glucose values. However, the apparatus need not include a blood glucose meter. In one alternative embodiment, the blood glucose

meter is separate from the apparatus and the patient manually enters measured blood glucose values into the apparatus through the keypad. In another embodiment, the blood glucose meter is connectable to the apparatus through a serial

5 input/output port for automated uploading of the blood glucose values. Similarly, in embodiments of the apparatus which include a modem, the modem need not be built into the apparatus. In alternative embodiments, the apparatus may be adapted to receive a separate modem card, as is well known in

10 the art.

Moreover, the apparatus is not limited to storing patient data relating only to blood glucose and insulin dose values. In alternative embodiments, the apparatus also stores

15 guidelines for diet, exercise, and other therapy parameters. Further, the apparatus may be programmed to prompt a patient for data relating to the therapy parameters and to display recommended guidelines to the patient.

20 Additionally, the invention may also be implemented as a simulation system for educating and training patients in blood glucose control. In the simulation embodiment, the insulin dose values are representative of simulated insulin doses and the blood glucose values are representative of

25 simulated blood glucose concentrations. The patient enters various insulin dose values and blood glucose values in the simulation system to learn their effect on his or her future blood glucose concentration.

30 Therefore, the scope of the invention should be determined not by the examples given but by the appended claims and their legal equivalents.